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BY CM/ECF
The Honorable Mitchell S. Goldberg
United States District Court
Eastern District of Pennsylvania
James A. Byrne U.S. Courthouse, Room 17614
601 Market Street
Philadelphia, PA 19106-1797

Re: *Arbutus Biopharma Corporation, et. al. v. Moderna, Inc., et. al.*
C.A. No. 22-252-MSG

Dear Judge Goldberg:

We write on behalf of Plaintiffs Arbutus and Genevant pursuant to Your Honor's order directing the parties to submit letter briefs regarding the impact of the Government's Statement of Interest on the scheduling of this matter. D.I. 51. The Government's Statement (D.I. 49) does not change the scope of this case or disturb the Court's holding last November that the resolution of Moderna's affirmative defense under 28 U.S.C. § 1498(a) "is not appropriate . . . in a Rule 12(b)(6) motion." D.I. 31 at 13. Indeed, as discussed below, both Moderna and the Government concede that regardless of § 1498(a), Plaintiffs' claims related to significant sales to the Government, as well as significant non-governmental sales, must be adjudicated here and not in the Court of Federal Claims. And in any event, the Government's Statement is merely one piece of evidence that the Court or jury eventually may consider, but it is not dispositive, particularly on the pleadings, of the crucial contested issue here: whether the accused manufacture, offers for sale, sale, and use of Moderna's COVID-19 vaccine was "for the Government" or for the U.S. population. Adjudication of that question is reserved for this Court. The Government's view is mere attorney argument entitled to no deference and, in any event, contradicts binding precedent that this Court previously followed and should not now ignore.

In denying Moderna's partial motion to dismiss, the Court correctly observed that § 1498(a) requires Moderna to make two independent showings: that its infringement of Plaintiffs' patents was (1) "for the Government," *and* (2) with the Government's "authorization or consent." 28 U.S.C. § 1498(a); *Sevenson Evnt'l Servs., Inc. v. Shaw Envt'l, Inc.*, 477 F.3d 1361, 1365 (Fed. Cir. 2007); D.I. 31 at 8. Despite the uniform body of precedent requiring both prongs of § 1498(a) to be met, the Government urges the Court to perform a "truncated inquiry" focusing entirely on the inclusion of "FAR 52.227-1" in the -0100 Contract between Moderna and the Government, without considering any other evidence. D.I. 49 at 9. According to the Government, FAR 52.227-1 definitively resolves the "authorization or consent" inquiry, and the Court has no further role to play regarding the other prong of § 1498(a)—whether Moderna's infringement was "for the Government"—simply because Moderna "compli[ed] with the contract's obligations." *Id.* at 10.

That is a radical departure from the law. Even if the Court could consider a single,

selectively produced document at the Rule 12 stage, the Government's "truncated inquiry" finds no support in *Sevenson*, the sole case cited in the Government's Statement for that proposition, nor anywhere else. The Government's reading, and the expansive application of § 1498(a) it now urges, is contrary to the statute's text and history, and also to *Larson v. United States*, 26 Cl. Ct. 365 (1992), as this Court found in denying Moderna's motion. D.I. 31 at 9–13 (analyzing *Larson*, *Advanced Software Design Co. v. Fed. Reserve Bank of St. Louis*, 583 F.3d 1371 (Fed. Cir. 2009), and *Saint-Gobain Ceramics & Plastics, Inc. v. II-VII Inc.*, 369 F.Supp.3d 963 (C.D. Cal. 2019)). As the Court held, whether Moderna's infringement was for the benefit of the U.S. population or the Government is a factual dispute that can only be resolved on a fully developed record. D.I. 31 at 13–14. The Government is not the trier of fact, and its opinion on the case law regarding § 1498(a), the subject of the majority of its Statement, is entitled to no deference.

If anything, the Government's Statement makes clear why Plaintiffs should be afforded an opportunity to develop a full factual record. Astonishingly, the Government's submission reveals that Moderna knew—while its motion "to dismiss *with prejudice* Plaintiffs' claims based on Moderna's sale and provision of COVID-19 doses to the U.S. Government" was pending, D.I. 17 at 14 (emphasis added)—that the Government had disclaimed authorization and consent under one of the two contracts between them. Even Moderna now agrees that Plaintiffs' claims regarding sales under the second contract should not be dismissed, Feb. 16, 2023 Tr. (Ex. 1) 28:7–14, such that its initial motion (never amended even upon execution of the second contract) sought improper relief. Yet Moderna never brought this fact to either Plaintiffs' or the Court's attention. Had the Court granted Moderna's motion without discovery—an approach Moderna advocated and still advocates—neither the Court nor Plaintiffs ever would have known that Moderna's request was, by its own belated admission, improper. The Government's revelation is precisely why courts routinely hold that the application of § 1498(a) should be decided at summary judgment, rather than on the pleadings. *Toxgon Corp. v. BNFL, Inc.*, 312 F.3d 1379, 1382 (Fed. Cir. 2002).

Nor would waiting to decide the application of § 1498(a) have a material impact on the scope of discovery in the case. While there is certainly discovery to be taken as to the application of § 1498(a) itself, *see infra* at 7, the core issues in the case—infringement, invalidity, and the reasonable royalty—will be unchanged irrespective of whether the Court ultimately determines that some damages should be collected in the Court of Federal Claims. For these reasons and the reasons that follow, Plaintiffs request that the Court resolve the parties' disagreements in the proposed case schedule, D.I. 46, and enter a scheduling order setting a date for trial.

I. Background and Procedural Posture

Plaintiffs filed their Complaint over a year ago asserting patents covering the lipid nanoparticle ("LNP") technology in Moderna's COVID-19 vaccine. Plaintiffs' LNP technology solved the key challenge underlying the new class of medicines to which Moderna's mRNA-based vaccine belongs: the protection of the fragile mRNA (and other nucleic acids) from degradation in the human body and the delivery of those molecules into human cells where they can exert their therapeutic effect. D.I. 1 ¶¶ 21–28. This lawsuit followed not only Moderna's refusal to negotiate a reasonable license to Plaintiffs' patents, but also its failed effort to invalidate certain claims of the patents-in-suit in *inter partes* review proceedings before the USPTO. D.I. 1 ¶¶ 31–38, 55–64. Moderna's failed IPR attacks and unsuccessful efforts to reverse them on appeal to the Federal

Circuit, 18 F.4th 1352 (Fed. Cir. 2021); 18 F.4th 1364 (Fed. Cir. 2021), leave Moderna statutorily estopped from advancing in this lawsuit its primary arguments against Plaintiffs' patents. 35 U.S.C. § 315. Moderna's effort to avert the estoppel flowing from those failed proceedings provide important clues as to why the Government and Moderna, as part of their ongoing, politically-charged negotiations,[1] would seek (improperly) to shift the billions of dollars of liability at issue away from Moderna and to the Government. *See infra* at 7.

Moderna moved for partial dismissal of Plaintiffs' Complaint on May 6, 2022, on the basis that all of its COVID-19 vaccine sales to the U.S. Government were subject to the so-called "government contractor defense" under 28 U.S.C. § 1498(a). Section 1498(a) is an affirmative defense that requires Moderna to prove that its infringement be (1) "for the Government" and (2) with "the authorization and consent of the Government." D.I. 17 at 10–11; 28 U.S.C. § 1498(a). In an effort to meet its burden, Moderna requested the Court take judicial notice of its "-0100 Contract" with the Government, including the incorporation of FAR 52.227-1. D.I. 17 at 7–8. Plaintiffs opposed because, as alleged in the Complaint, Moderna's vaccines sales, while funded *by* the Government, were not *for* the Government—but "for the benefit of individual vaccine recipients in the United States." *E.g.*, D.I. 21 at 3, 7, 9–16; D.I. 1 ¶ 51; *see also Larson*, 26 Cl. Ct. at 369. Plaintiffs also pointed out that, in addition to the sufficiency of their allegations, discovery would be needed to ascertain whether in fact all of Moderna's government sales were both "for the Government" and with the Government's "authorization or consent." D.I. 21 at 17–20.

On November 2, 2022, the Court denied Moderna's motion, agreeing that "this case [is] more akin to *Larson* than *Advanced Software Design* or *Saint-Gobain Ceramics*" and that whether Moderna's infringement was "for the Government" and with its "authorization or consent" were disputes "best considered under a more fully developed record." D.I. 31 at 12, 16. Unbeknownst to the Court or Plaintiffs, Moderna and the Government executed the "-0017 Contract" months earlier, in July 2022 for 300 million more doses.[2] As the Government's Statement makes clear, D.I. 49 at 4, and Moderna agrees, Feb. 23, 2023 Tr. (Ex. 1) 28:7–14, § 1498(a) does not apply to the -0017 Contract, such that even if Moderna's partial motion were granted, this Court would still be left with claims to adjudicate, as to sales to the Government and others.

II. The Government's Statement Does Not Control the Application of § 1498(a) or Address the Full Scope of Its Requirements.

A. The Government improperly vitiates "for the Government" from § 1498(a).

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[1] *See, e.g.*, https://www.bostonglobe.com/2023/01/25/business/two-senators-accuse-moderna-greed-its-plan-quadruple-covid-vaccine-cost/ (**Exhibit 4**); https://www.sanders.senate.gov/wp-content/uploads/Moderna-Letter-01.09.20231.pdf **(Exhibit 5**); https://www.warren.senate.gov/imo/media/doc/2023.01.24%20Letter%20to%20Moderna%20re%20COVID%20Vaccine%20Price%20Hikes.pdf (**Exhibit 6**).

[2] https://investors.modernatx.com/news/news-details/2022/Moderna-Announces-New-Supply-Contract-With-The-U.S.-Government-For-An-Initial-66-Million-Doses-Of-A-Moderna-Bivalent-Covid-19-Booster-Vaccine-With-Options-For-U.S.-Government-To-Purchase-Up-To-An-Additional-234-Million-Doses/default.aspx (**Exhibit 7**).

The Government's Statement offers no reason to depart from the Court's prior ruling. The Government focuses heavily on the incorporation of FAR 52.227-1 in the -0100 Contract. D.I. 49 at 1–4, 8–10. But the incorporation of that provision is not new. Moderna's motion made FAR 52.227-1 its centerpiece, D.I. 17 at 6, 12–14, and the Court rejected that provision as singularly dispositive of § 1498(a)'s application, because the statute requires more than authorization and consent: the infringement must also be for the benefit of the Government, D.I. 31 at 13–14.

Rather than address that distinct legal requirement Moderna failed to meet, D.I. 31 at 13, the Government advances the unprecedented theory that when FAR 52.227-1 is present, "the 'for the Government' inquiry" under § 1498(a) should "collapse[] into the 'authorization and consent' inquiry." D.I. 49 at 9. The Government's interpretation of precedent manifestly cannot supplant the Court's. And the Government is wrong. Its sole support is *Sevenson*, a case that this Court cited for the exact *opposite* point: that "[a] defendant" like Moderna "bears the burden of establishing that '(1) the [infring]ing use is "for the Government" and (2) the [infringing] use is "with the authorization and consent of the government."'" D.I. 31 at 8.

Sevenson on its face does not support the Government's position. There, as in all of the § 1498(a) cases cited by Moderna and the Government, the Federal Circuit separately analyzed *both* prongs of the statutory inquiry. The court began its analysis by expressly rejecting the appellee's argument that "for the Government" requires the "primary purpose" of the contract be to benefit the Government. 477 F.3d at 1365–66. In doing so, the court simply adhered to the statutory text, which imposes no such requirement. *Id.* The Federal Circuit proceeded to address whether there was a genuine dispute as to the second prong—whether the infringement was "with the authorization and consent of the Government." *Id.* at 1367–68.

In doing so, the Court of Appeals did *not* find that a "truncated inquiry" under § 1498(a) would be appropriate. Instead, as the Government's own parenthetical quote from *Sevenson* makes clear, D.I. 49 at 9, to the extent courts have "bypassed a separate inquiry into whether infringing activity was performed 'for the Government,'" they have done so only "where infringing activity has been performed by a government contractor pursuant to a government contract *and for the benefit of the Government*." 477 F.3d at 1366 (emphasis added). In other words, in a case like *Sevenson* where the benefit to the Government is undisputed under the correct legal standard—the use of patented technology to remediate toxic waste *on a parcel of Government property*—and the patent owner's only argument rests on an extrastatutory requirement that the "primary purpose" of the infringement be "for the Government," there is no factual dispute that the "for the Government" prong of § 1498(a) is met. Put another way, as with all legal tests, where one prong of a two-prong test is not disputed (or not disputed under the correct legal standard), the inquiry turns on the single, disputed prong. Here, however, the parties dispute—fiercely—the "for the Government" prong. The posture in which *Sevenson* was decided—summary judgment—also confirms that resolution of the "for the Government" inquiry cannot be "truncated" merely by the Government's after-the-fact say-so. *See also infra* at 7.

Given *Sevenson*'s plain import, it is unsurprising that counsel for the United States backtracked from the Statement during the February 16, 2023 conference, stating that *Sevenson* had merely "suggested" the possibility of the Government's "truncated inquiry." Feb. 16, 2023 Tr. (Ex. 1) 26:14–19. In reality, *Sevenson* "suggested" no such thing. Every court to address the

§ 1498(a) inquiry, before *Sevenson* and after, has reiterated that two distinct prongs must be satisfied for its invocation. *E.g.*, *Sevenson*, 477 F.3d at 1365; *Advanced Software*, 583 F.3d at 1376; *Saint-Gobain*, 369 F.Supp.3d at 970; *IRIS v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014); *Hughes Aircraft Co. v. United States*, 534 F.2d 889, 898 (Ct. Cl. 1976). Not even Moderna, in multiple briefs, D.I. 17, 23, has argued that the Court should ignore this avalanche of precedent or "collapse" the statute's two-pronged test into one. It is a simple matter of logic that "standing alone, a governmental grant of authorization or consent does not mean that the alleged use or manufacture is done 'for the United States' under § 1498(a)." *IRIS*, 769 F.3d at 1362.

During the February 16 hearing, the Government also urged the Court to look to *Advanced Software*. Feb. 16, 2023 Tr. (Ex. 1) 26:14–19. That case does not support the Government's position either. As in *Sevenson*, the court in *Advanced Software* carefully examined the factual record to ascertain whether both of the statutory requirements "for the Government" and "with the authorization or consent of the Government" were met. That analysis considered testimony from a U.S. Treasury official, as well as the benefit to the Government in the form of detecting fraudulent checks purportedly from the U.S. Treasury, to resolve summary judgment, not a motion to dismiss under Rule 12(b)(6). *Advanced Software*, 583 F.3d at 1374, 1376 (quoting *Sevenson*'s legal standard as providing "two criteria for application of § 1498(a) to activity of private parties").

The Government's belated invitation to overturn decades of precedent to erase the "for the Government" prong of § 1498(a) is as transparent as it is baseless. Rather than finding any case law support, the Government's misreading of *Sevenson* was first advanced in a 2016 Yale Law Journal article—and later by a Senator—urging the Government to pursue a price reduction scheme by invoking § 1498(a) to buy "generic versions of [approved medicines] at less than 1% of their list price plus a reasonable royalty." H. Brennan, A. Kapczynski, C.H. Monahan & Z. Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 Yale J.L. & Tech. 275, 275 (2016) ("Yale Article"); Letter from Senator Elizabeth Warren to Xavier Becerra (Apr. 22, 2022), (**Exhibit 2**). The authors of that article quoted the same portion of *Sevenson* as the Government does now to assert that "where the infringing party has shown that they are acting pursuant to a contract with the federal government, courts typically assume use 'for' the government without further inquiry.'" Yale Article at 333 & nn.271–72. A month after Moderna filed its reply brief, D.I. 23, a faction of legislators again urged the Department of Health and Human Services, the agency on behalf of which the Government submitted its Statement, to "use compulsory licensing under 28 U.S.C. § 1498(a) . . . to lower prescription drug prices." Letter to the Honorable Xavier Becerra (June 23, 2022) (**Exhibit 3**).

The reason that the Government's Statement—parroting the law review article—urges this Court to erase the "for the Government" prong of the § 1498(a) inquiry, is that medical treatments and interventions, such as Moderna's COVID-19 vaccine, fail to satisfy that prong. The law could not be clearer: "Medical care is provided for the benefit of the patient, not the government." *Larson*, 26 Cl. Ct. at 369. Moderna's inability to satisfy § 1498(a) is no reason to change it outside of the proper legislative avenue. The Government's argument is nothing more and nothing less than an invitation to rewrite the statute for political purposes, as ensuing commentators—including the former Chief Judge of the Court of Federal Claims herself—have explained. Chief Judge Braden and others have criticized a reading of *Sevenson* that permits the Government to abrogate unilaterally the statutory text requiring that the infringing conduct be "for the Government," as the

Government urges here, and endorsed this Court's interpretation of precedent. Susan G. Braden & Joshua A. Kresh, *Section 1498(a) is Not a Rx to Reduce Drug Prices*, 77 Food & Drug L.J. 274, 283 & n.53, 285 n.74 (2022) (**Exhibit 11**). Chief Judge Braden further observed that "continued pressure on the executive branch to exert 28 U.S.C. § 1498(a) should be expected." *Id.* at 275.

That "continued pressure" ostensibly has succeeded, and the executive branch (through the Government's Statement) now beseeches this Court to ignore the text of § 1498(a) and its own prior interpretation of *Sevenson* and *Larson* that are inconsistent with the Government's apparent policy goal of expanding § 1498(a) into the realm of medical care. No court has advanced the view of § 1498(a) that the Government now urges. Contra the Government's suggestion, "it is emphatically the province and duty of the judicial department," not the executive or legislative branches, "to say what the law is." *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803).

B. This Court correctly applied the controlling precedent in *Larson* to the facts alleged in the Complaint.

Aside from erasing the "for the Government" test, the Government offers no new response to *Larson*, Plaintiffs' lead case that the Court carefully considered in denying Moderna's partial motion to dismiss, D.I. 21 at 10, D.I. 31 at 12. The *Larson* Court determined that the provision of infringing medical equipment to patients through Medicare and Medicaid was not "for the Government" because "the fact that the government has an interest in [a] program generally, *or funds or reimburses all or part of its costs*, is too remote to make the government the program's beneficiary for the purposes underlying § 1498." 26 Cl. Ct. at 369 (emphasis added). *Larson*'s reasoning applies full force, notwithstanding the Government's Statement. As in *Larson*, "the benefit and convenience," *id.*, of "free public distribution" of Moderna's vaccine, D.I. 49 at 10, funded or reimbursed by the Government, flowed to the "patient and provider, *with no benefit to the government*," 26 Cl. Ct. at 369 (emphasis added). Again, "[m]edical care is provided for the benefit of the patient, not the government." *Id.* All that Moderna and the Government have cited to date is the generalized programmatic interest in "thwart[ing] the COVID-19 pandemic," D.I. 49 at 10, which this Court properly found is insufficient. *See also Windsurfing Int'l., Inc. v. Ostermann*, 534 F.Supp.581, 588 (S.D.N.Y. 1982).

The Government downplays *Larson* by reprising Moderna's failed argument that *Larson*'s facts can be distinguished by the absence of an express government contract. *See* D.I. 49 at 12; D.I. 23 at 3–4. But that fact was irrelevant in *Larson*, and neither Moderna nor the Government cite a case where it has proven dispositive. The Government and Moderna's argument seems to be that the invocation of FAR 52.227-1 is enough on its own to definitively establish the applicability of § 1498(a). That express Government contract may be relevant to the "authorization and consent" prong of the test, but it does not change the fact that, as to the first prong, "[m]edical care is provided for the benefit of the patient, not the government." *Larson*, 26 Cl. Ct. at 369. The patient receives that benefit identically, without regard to whether the Government signed a contract or provides funding or a reimbursement. *Arlton v. Aerovironment, Inc.*, 2021 WL 1589302, at *7–8 (C.D. Cal. Apr. 22, 2021) (requiring and finding "more than incidental benefit" to the Government, notwithstanding contract with FAR 52.227-1).

In reality, the key distinction between this case and the cases relied upon by the

Government and Moderna finding § 1498(a) to be applicable is that there is (at best for Moderna) a genuine factual dispute regarding whether Moderna's infringement was "for the Government." In each of those cases, the Government benefit was indisputable. In *Saint-Gobain*, the infringing sapphire sheets were used in F-35 fighter jets; in *Advanced Software*, the technology at issue was to detect fraudulent U.S. Treasury checks; in *Sevenson*, the infringing "phosphoric-acid based stabilization system" was to remediate toxic waste at a Government-owned property. The only case analogous to the facts here—subsidized private medical treatment—is *Larson*. The Government's position that a "contractor's compliance with the contract's obligations alone" is sufficient to invoke § 1498(a) whenever a clause like FAR 52.227-1 is present, D.I. 49 at 10, fully embraces the error that the Court observed in Moderna's nearly identical position, *i.e.*, "that every government-funded product used to advance any policy goal articulated by the U.S. Government—such as IV needles to fight HIV to cancer drugs to fight the war on cancer—would be subject to a § 1498(a) defense," D.I. 31 at 13. That misapplication of § 1498(a) was wrong in Moderna's motion, and it fares no better now repeated by the Government (which apparently seeks to expand § 1498(a) to the examples identified by the Court that are plainly beyond the reach of the statute).

C. The Government's Statement does not address Plaintiffs' indirect infringement allegations.

Even as the Government's Statement errs regarding the application of § 1498(a) to the sale of Moderna's vaccine doses to the Government, it is completely silent about an entire, and distinct, category of infringement alleged in the Complaint: Moderna's indirect-infringement liability for inducing and contributing to direct infringement by the numerous non-governmental actors involved in the distribution and administration of Moderna's infringing vaccine. *E.g.*, D.I. 1 ¶ 9. None of these infringing uses are "by or for the United States"—the Government is nowhere to be found. The Government never asserts otherwise. Thus, separate and apart from any other acts of infringement addressed by the Government, there can be no doubt that these acts of infringement, *which apply to every dose of the accused vaccine* ever used in the United States, are not subject to § 1498(a). The law is clear that "section 1498(a) is a waiver of sovereign immunity only with respect to a direct governmental infringement of a patent . . . the Government is not liable for its inducing infringement by others, for its conduct contributory to infringement of others." *Decca v. United States*, 640 F.2d 1156, 1167 (Ct. Cl. 1980); *Madey v. Duke Univ.*, 307 F.3d 1351, 1359 (Fed. Cir. 2002) (§ 1498(a) "acts as a waiver of sovereign immunity" and "waivers of sovereign immunity are to be strictly construed."). The authority cited by the Government, D.I. 57 at 3, does not address liability for indirect infringement by use of a patented invention by private parties, as alleged in Plaintiffs' Complaint here. Accordingly, even were government sales under one contract somehow subject to § 1498(a) (they are not), Moderna would remain accused of indirect infringement with respect to every dose, and such allegations would *not* be subject to § 1498(a).

III. The Government's Statement Underscores that Discovery is Needed to Determine the Applicability of § 1498(a).

In denying Moderna's motion, the Court held that "this dispute is not appropriate for resolution in a Rule 12(b)(6) motion" and that the "dispute should be resolved by summary judgment rather than on a motion to dismiss." D.I. 31 at 13; *Toxgon*, 312 F.3d at 1382. In *Saint-Gobain*, a case cited by both the Government and Moderna, D.I. 49 at 10, the court "converted

defendants' motion to dismiss into a motion for summary judgment" and "directed the parties to conduct discovery and submit supplemental briefing on the applicability of § 1498." 369 F.Supp.3d at 966. The Government's Statement neither requires nor warrants departure from the Court's earlier decision. Indeed, the revelation that Moderna was seeking dismissal with prejudice of all claims relating to sales to the Government, while knowing the Government had expressly revoked any authorization and consent as to certain sales, only underscores why courts do not make legal determinations on less than a full record. Feb. 16, 2023 Tr. (Ex. 1) 28:7–14.

Discovery in this case is still needed into both prongs of Moderna's § 1498(a) defense—as it is with respect to all of the disputed issues of infringement, validity, and damages. As to the "authorization and consent" prong, although the Government has offered to produce unredacted versions of the contracts, it still has not done so. It has offered no legal basis for the Court to consider those documents—and those documents alone—in deciding whether Moderna has met its burden to establish an affirmative defense at the pleading stage. And Plaintiffs have been afforded no opportunity to take discovery into whether there are any formal or informal communications outside of the -0100 Contract that might modify or limit the scope of the Government's authorization and consent.

But even if authorization and consent were present, extensive fact discovery remains as to whether Moderna can meet the "for the Government" prong of § 1498(a). Tellingly, the Government's Statement entirely avoids the factual dispute in favor of a contorted interpretation of *Sevenson* that simply reads the inquiry out of the statute. And here, the question of whether the Government is more than an "incidental" beneficiary is hotly disputed. That distinguishes this case from those in which courts have relied on Statements of Interest. In *Arlton*, cited by the Court, D.I. 31 at 15, for example, the alleged infringement involved "Mars Helicopters" built for NASA, 2021 WL 1589302, at *7.[3] In *IRIS v. JAL*, referenced by Moderna during the hearing, Feb. 16, 2023 Tr. (Ex. 1) 20:20–21:3, the infringement involved the "uniquely governmental function" of border security and the "quasi-governmental function" of screening for fraudulent passports, 469 F.3d at 1362. As *Larson* makes clear, the alleged infringement for healthcare here is far different. And as both the Government and Moderna acknowledged at the Court's conference, the Government's Statement is not conclusive. *See* Feb. 16, 2023 Tr. (Ex. 1) 20:14–19 ("not accepted without question"), 26:1–6 ("the Court always has a role in determining whether § 1498 applies"); *see also IRIS*, 769 F.3d at 1363 ("the government's statement is not dispositive").

Plaintiffs thus intend to take discovery relevant to the application of § 1498(a) in this case, including (i) the complete and unredacted terms of Moderna's contracts with the Government and any other related agreements and communications; (ii) the negotiations that culminated in the terms of those agreements; (iii) the nature and extent of the Government's involvement in the development and specifications of the infringing vaccine, (iv) how the purchased doses were distributed and to whom—whether to customers of drug stores, grocery stores, private medical practices, or others; (v) Moderna's and the Government's respective understandings of who were

[3] *Arlton* underscores the need for discovery as the court in that case (1) vacated summary judgment after the defendant "publicly showcased" a new product that it had failed to disclose and (2) ordered limited discovery on that product. 2021 WL 4902186, at *3–5 (C.D. Cal. June 24, 2021).

the true beneficiaries of the contract; and (vi) any discussions of Plaintiffs' patents, including efforts to avoid the effects of *inter partes* review estoppel by shifting liability. *See, e.g.*, Order, *Racing Optics, Inc. v. Clear Defense, LLC*, No. 16-cv-288, D.I. 22, D.I. 23 (M.D.N.C. Sept. 30, 2016 & Oct. 13, 2016) (ordering production of "all of [defendant's] communications with the Government concerning sales of the Accused Products" and depositions of "persons with knowledge of the facts and documents related to [defendant's] § 1498(a) defense."); *Crater Corp. v. Lucent Techs., Inc.*, 1999 WL 33973795, at *2–3 (E.D. Mo. Aug. 25, 1999) (granting discovery on § 1498(a), including evaluating the Government's claim to privilege based on state secrets).

The current circumstances especially warrant discovery. The Government's Statement comes nearly a year after Moderna filed its motion, in the midst of ongoing negotiations between them, the day before Moderna announced it would make vaccines "available at no cost for insured people," and after paying $400 million to settle part of an ongoing patent dispute.[4] It would hardly be surprising, given the attendant media and political scrutiny, for the Government and Moderna to have discussed the Government's willingness to take on potentially billions of dollars of liability in exchange for concessions from Moderna. Plaintiffs, of course, can only surmise what negotiations between Moderna and the Government contain—the purpose of discovery is to establish those contents as a factual matter. Indeed, Moderna's decision not to advise Plaintiffs and the Court that the Government withdrew any potential authorization in the July 2022 contract, while continuing to seek what Moderna now acknowledges was improper dismissal of Government sales, reinforces the need for discovery. Feb. 16, 2023 Tr. (Ex. 1) 28:7–14.

IV. Judicial Efficiency Would Not Be Served by Deciding the Application of § 1498(a) Before Discovery.

Moderna does not dispute that significant allegations of infringement remain to be tried in this Court regardless of whether § 1498(a) ultimately applies to sales under the -0100 Contract. Feb. 16, 2023 Tr. (Ex. 1) 28:7–14. The Government's Statement confirms that this case will concern not only Moderna's liability for contributing to and inducing uses of its vaccine, but also its forthcoming sales in the private insurance market, and also sales to the Government for which the latter has disclaimed all patent infringement liability—*i.e.* sales pursuant to the -0017 Contract. As a result, even if the Government and Moderna's novel and unsupported interpretation of § 1498(a) were accepted, the Court would still have to preside over a case regarding infringement, validity, and damages with respect to the patents-in-suit, and no efficiency will be gained from deciding the application of § 1498(a) now as opposed to at summary judgment or trial.

Nor would proceedings in this Court be duplicative or *de minimis*. The Government's Statement does not contest that sales or offers for sales relating to hundreds of millions of doses, as well as infringing uses for every dose, must be tried in this forum. *See* note 2, *supra*. And there is no co-pending case in the Court of Federal Claims at the present time, so any case would

[4] https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2023/Modernas-Commitment-to-Patient-Access-in-the-United-States/default.aspx (**Exhibit 8**); https://www.wsj.com/articles/moderna-considers-price-of-110-130-for-covid-19-vaccine-11673289609 (**Exhibit 9**); https://www.nytimes.com/2023/02/23/science/moderna-covid-vaccine-patent-nih.html (**Exhibit 10**).

necessarily be far behind this suit; duplicative litigation could result only if Moderna's motion were granted. As the Third Circuit has emphasized, "[i]n all cases of federal concurrent jurisdiction, the court which first ha[d] possession of the subject *must* decide it." *EEOC v. University of Pennsylvania*, 850 F.2d 969, 971 (3d Cir. 1988) (emphasis added).

Moreover, to the extent there is any risk of duplicative litigation, it favors proceeding in this Court, rather than the Court of Federal Claims, because certain issues have already been adjudicated as between Plaintiffs and Moderna. Specifically, as a result of its failed challenges in the Patent Office, Moderna is statutorily estopped from raising certain invalidity defenses under 35 U.S.C. §§ 102 and 103. *See* 35 U.S.C. 315(e)(2). Common law principles of collateral estoppel also apply to arguments that Moderna has raised and lost before the agency. *See MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1376 (Fed. Cir. 2018). The effect of these estoppels would be to streamline this litigation considerably.

Revealingly, in response to this Court's query, the Government declined to agree not to re-litigate issues of infringement and validity, responding that it had not yet had occasion, in the year since this case was filed, to analyze those issues that bear on billions of dollars of liability it now seeks to inherit. Feb. 16, 2023 Tr. (Ex. 1) 24:23–25:4. The Government's refusal to commit to being bound by estoppels that apply to Moderna improperly invites duplicative litigation that Congress deemed inappropriate. Plaintiffs have prevailed on the issues of obviousness and anticipation, and the notion that the Government can step into Moderna's shoes and attempt to avoid Moderna's estoppels is as unfair as it is inefficient. Judicial efficiency is promoted best by proceeding in this Court, leaving any sales subject to § 1498(a) left at its conclusion limited to the quantification of damages owed by the Government to Plaintiffs in the Court of Federal Claims.

V. Plaintiffs Would be Prejudiced by Pursuing Relief in the Court of Federal Claims.

The tactical advantage of attempting to avoid estoppel is hardly the only reason that Moderna (and now the Government) have sought dismissal under § 1498(a). Litigation in this forum carries both procedural and substantive advantages that would not be afforded to Plaintiffs in the Court of Federal Claims, and Plaintiffs should not be deprived of their rights in this forum on an undeveloped record. For example, Plaintiffs are entitled under the Seventh Amendment to trial by jury in this Court; proceedings in the Court of Federal Claims, on the other hand, carry no such right. *E.g.*, *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 377 (1996). Plaintiffs also are seeking enhanced damages for willful patent infringement, potentially trebling the billions of dollars of compensatory liability. *E.g.*, D.I. 1 ¶¶ 31–38, 39–50, 77, 82–83, 96, 101–02, 118, 123–24, 142, 147–48, 161, 166–67, 186–87. This remedy is unavailable in a suit against the Government in the Court of Federal Claims. *See, e.g.*, *Return Mail, Inc. v. USPS*, 139 S. Ct. 1853, 1866–67 (2019). And, as above, Plaintiffs would be prejudiced by any attempt by the Government to relitigate issues of infringement and validity that had been established in other fora.

Before the Court determines whether Plaintiffs should be deprived of these aspects of litigation in this forum, Plaintiffs should be afforded a full and fair opportunity to develop a factual record for the Court to consider when deciding the important question of the application of § 1498(a) to the acts of infringement alleged in this case.

Respectfully submitted,

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